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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,841	01/12/2001	Susan Dobbs	PCS 10348ADAM	1916

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EXAMINER	
BROWN, TIMOTHY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/759,841	DOBBS ET AL.	
	Examiner	Art Unit	
	Tim Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *5 and 12-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/27/03 & 12/4/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to Applicants' Election mailed May 7, 2004. Applicants elected to prosecute the invention of claim set 1, with traverse. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Note that Applicants failed to elect one of the species associated with group 1 as required by the restriction (*see* pp. 4-5). In the interest of compact prosecution, the first species (drawn to a detectable fluorescent label) has been examined as if elected by Applicants.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copies of the foreign priority documents have been received.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite in the recitation of "low affinity binding." This language fails to adequately define the scope of the invention because it does not indicate the nature of the interaction between CCR5 and gp120. Moreover, "low" is a relative term that is

not defined by the claim, and the specification does not provide a specific standard for evaluating a definite range to which the term "low" refers.

Claim 1 is further indefinite in that it provides that the agent is "capable of modulating." This language does not particularly point out and distinctly claim the invention because it is not clear whether the "agent" actually has the ability to modulate the interaction of CCR5 and gp120. Therefore, the language "capable of" does not provide any indication of what the "agent" has to actually accomplish in order to be within the scope of the claim.

Claim 1 is also indefinite in that it does not include a resolution step. Claim 1 is directed to a method "for determining whether an agent is capable of modulating the interaction of CCR5 and gp120." However, claim 1 fails to recite any resolution step wherein the interaction between CCR5 and gp120 is actually detected or otherwise observed. Therefore, it is unclear how claim 1 determines the agent's activity without actually observing the claimed interaction. Accordingly, claim 1 does not particularly point out and distinctly claim the invention.

Finally, claim 1 is indefinite in the recitation of "modulating" in line 1, and "modulates" in line 10. This results because it is unclear whether "modulating" refers to inhibiting, or enhancing, the interaction between CCR5 and gp120. Thus, the language "capable of modulating" renders the scope of claim 1 indefinite.

Claim 7 is indefinite for reciting a relative term of degree. Claim 7 recites "high affinity binding" in line 2. As with claim 1, the term high is a relative term of degree that is not supported by a specific standard in Applicants' specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Wu et al. (U.S. Pat. No. 6,528,625 B1).

Wu et al. teaches an assay method for determining whether an agent is capable of modulating the interaction of CCR5 with gp120, the method comprising: incubating the agent with CCRS and gp120 to form a first reaction mixture, determining whether said agent modulates the interaction of CCR5 with gp120, wherein said gp120 is associated with CD4 (col. 23, lines 19-26).

Note that the limitation "wherein said interaction is a low affinity binding" has not been given patentable weight. This results because the language "low affinity binding" does not provide any clarity as to the nature of the CCR5/gp120 interaction. Therefore, this language does not further limit claim 1 for purposes of this art rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-4 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (U.S. Pat. No. 6,528,625 B1) in view of LaRosa (U.S. Pat. No. 6,312,689 B1).

Claims 2-4 and 6-11 further narrow claim 1 by adding, among other things, a second detectable ligand to the reaction mixture. The second detectable ligand comprises an antibody that is capable of binding to gp120, or binding to the first antibody.

Wu et al. teach all the features noted above. Wu et al. do not expressly teach the claimed second detectable ligand. However, LaRosa teaches a method for detecting the interaction of CCR2 with α-CCR2 antibody using a labeled secondary antibody that specifically binds to α-CCR2. Wu et al. indicate that "[t]he ability of the antibody . . . to inhibit . . . can be assessed using these or other suitable methods" (col. 23, lines 25-27). Moreover, it is within the knowledge generally available in the immunoassay art that a secondary antibody reaction can be used to enhance immunoassay sensitivity. Therefore, at the time of Applicants' invention, it would have been obvious to one of ordinary skill in the art to modify Wu et al. to include the used of the claimed second detectable ligand (i.e. antibody) as taught by LaRosa.

Note that the limitation "wherein said binding is high affinity binding" from claim 7 has not been given patentable weight. This results because the language "high affinity biding" does not provide any clarity or limitation as to the interaction between the first antibody and gp120. Therefore, this language cannot provide any patentable distinction over the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 9/7/04